Maryland Board of Pharmacy
Public Board Meeting
Minutes

Date: September 20, 2013

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	**Commissioner**	✓		**2**	**1**
Finke, H.	**Commissioner/Secretary**	✓		**3**	**0**
Gavgani, M. Z.	**Commissioner/Treasurer**	✓		**3**	**0**
Israbian-Jamgochian, L.	**Commissioner/President**	✓		**2**	**1**
Jones, David H.	**Commissioner**	✓		**3**	**0**
Rochester, C.	**Commissioner**	✓		**2**	**0**
Roy, S.	**Commissioner**	✓		**2**	**0**
Smith, J.	**Commissioner**	✓		**1**	**2**
Souranis, M.	**Commissioner**	✓		**3**	**0**
St. Cyr, II, Z. W.	**Commissioner**	✓		**3**	**0**
Board Counsel					
Bethman, L.	**Board Counsel**	✓		**3**	**0**
Felter, B.	**Staff Attorney**	✓		**3**	**0**
Board Staff					
Naesea, L.	**Executive Director**	✓		**2**	**1**
Wu, Y.	**Compliance Manager**	✓		**1**	**2**
Waddell, L.	**Licensing Manager**	✓		**3**	**0**
Gaither, P.	**Administration and Public Support Manager**	✓		**3**	**0**
Jeffers, A.	**Legislation/Regulations Manager**	✓		**3**	**0**
Johnson, J	**MIS Manager**	✓		**3**	**0**

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
I. Executive Committee Report(s)	A. L. Israbian-Jamgochian, President	*(Note: T*he Board of Pharmacy held the September, 2013 public board meeting at the University of Maryland Eastern Shore (UMES) School of Pharmacy) *Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.* 1. L. Israbian-Jamgochian called the Public Meeting to order at 10:00 a.m. 2. L. Israbian-Jamgochian reminded all guests to sign the guest log and to indicate whether they would like continuing education credits. 3. Members of the Board with any conflict of interests relating to any item on the agenda were advised to notify the Board. 4. L. Israbian-Jamgochian reported that all handouts were to be returned by attendees when they leave the meeting. 5. L. Israbian-Jamgochian thanked the UMES School of Pharmacy, , especially: Nicholas R. Blanchard, PharmD, MEd, Dean, School of Pharmacy and Health Professions; Ms. Annette Rogers Administrative Assistant to the Associate Dean for Professional Affairs at the School of Pharmacy; and Mrs. Sharon Burke, Information Technology Specialist for the School of Pharmacy for all of their help and assistance in the preparation and hostingof the Board of Pharmacy's September, 2013 meeting. 6. UMES School of Pharmacy Dean Blanchard spoke briefly		

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		and acknowledged the UMES School of Pharmacy staff and students and thanked the Board of Pharmacy for travelling to UMES to hold its Board Meeting. 7. Review and approval of August 21, 2013 public board meeting minutes. August 21, 2013 public board meeting minutes was approved as submitted.	Motion by M. Souranis to approve the August 21, 2013, public board meeting minutes as presented. Motion was seconded by D. Jones	Motion was approved.
II. A. Executive Director's Report	L. Naesea, Executive Director	**Operations Updates –** 1. L. Naesea thanked all UMES students and staff stating that the Board of Pharmacy is excited about bringing its public board meeting to the students and staff of UMES School of Pharmacy as well as to the general public on Maryland's eastern shore. 2. L. Naesea welcomed Serena Pu, from the University of Maryland School of Pharmacy at Baltimore, who is a student intern at the Board of Pharmacy. **Meeting Updates** - 1. L. Naesea will be attending NABP's Executive Director Conference next week, September 22 and 23, 2013 in Chicago, IL. 2. The Controlled Dangerous Substance Integrated Unit (CDSI) will hold its next meeting on September 26, 2013. The CDSIU is comprised of many state boards and departments who have joined together to try to assure that CDS drugs are not being abused. The various state boards and units under the Department of Health and Mental Hygiene share information and alert the other boards of any on-going investigations that may impact their respective units. 3. NABP District 2 Annual Conference will be held October 17		

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		– 19, 2013 in Bar Harbor, Maine. Commissioner H. Finke and L. Naesea will be attending this conference. 4. Citizens Advocacy Center meeting on October 29-30, 2013 will educate consumer board members on how to best represent State citizens who are impacted by the laws and rules considered by health occupation boards. Consumer Board Commissioner, Z. St. Cyr, II will be attending this meeting in Seattle, WA. 5. New Board member orientation is being held November 4, 2013. L. Naesea strongly urged new Board of Pharmacy commissioners to attend the meeting. The meeting reviews the roles of Board members, conflicts of interest issues and other matters of importance to for new commissioners serving on health occupation boards in Maryland.		
B. Administration & Public Support	P. Gaither, Administration & Public Support Manager	**1. Personnel Updates** The Board currently has 24 permanent positions, which the state of Maryland labels as PINS. The Board recently filled two PIN vacancies. One PIN was filled for the 50% pharmacist inspector, by Umber Chaudry. She will begin work on October 2, 2013. The second PIN was filled was by the Licensing Secretary, Janelle Jamerson who began work at the Board on September 4, 2013. In the near future the Board plans to recruit four new positions to work in the Compliance Unit pertaining to Sterile Compounding. Final approval from the Department of Budget and Management must be received before they may be hired.		
C. Management Information **Sy**stems	John Johnson, MIS Manager	J. Johnson reported on the on-going scanning project and noted that there are approximately 2 million documents that need to be reviewed, purged and/or scanned. J. Johnson stated that 5 temporary employees are being recruited to assist in preparing the documents under Maryland Records Retention and Disposal requirements for the major scanning project. • J. Johnson reported on the Board's new software application		

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		called MyLicense Office (MLO) installed by the vendor System Automation (SA). He noted that many of glitches that the Board has had with MLO have been corrected with support from SA. The support included upgrades and training of the Board's MIS staff over the past few months. The Board will be going into production with the upgrades next Saturday. J. Johnson lastly reported that the Board's contract with SA is being reviewed and there may be some additional support under the contract which SA may be required to give to the Board which includes additional on-line renewal configurations.		
D. Licensing	L. Waddell, Licensing Manager	Monthly Statistics for August, 2013. Pharmacists: • New Applications – 137 • Renewals – 362 • Total Licensed – 9643 Pharmacists Administer Vaccinations: • New Applications – 94 • Renewals – 1 • Total Certified - 3326 Technicians: • New Applications – 203 • Renewals – 282 • Total Registered –8526 Student Technicians • New Applications – 35 • Renewals – 1 • Total Registered – 841 Pharmacies: • New Applications – 30 • Renewals – 0		

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		• Total Pharmacies- 1943 Distributors: • New Applications – 12 • Renewals – 45 Total – 1085		
E. Compliance	Y. Wu, Compliance Manager	1. Monthly Statistics for August, 2013 <u>Complaints & Investigations</u>: New Complaints- 40 Resolved (Including Carryover) – 35 Final disciplinary actions taken – 9 Reversal – 0 Summary Actions Taken – 1 <u>Inspections:</u> 122 Annual Inspections- 112 Opening Inspections- 9 Closing Inspections - 0 Relocation Inspections- 0 Board Special Investigation Inspections – 1 Division of Drug Control Closing Inspections: 3		
	Y. Wu, Compliance Manager reporting for PEAC	• Total Pharmacist Rehabilitation Committee Clients – 1 • Pharmacist Clients – 17 • Technician Clients – 0 • Pharmacy Student Clients – 0 • Clients Monitored by Board Req. PEAC Assistance – 1 • Drug Testing Results – 24 • Number of Positive Results – 0 • Discharged Clients/Closed Cases – 1		

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F. Legislation & Regulations	A. Jeffers, Legislation & Regulations Manager	**REGULATIONS: (6 open chapters)** **10.34.03 – Inpatient Institutional Pharmacies** Published June 28, 2013. No comments received. Notice of Final Action submitted with May 31, 2014 effective date. **10.34.19 Sterile Pharmaceutical Compounding** Board approved draft revisions at May 15, 2013 Board Meeting. Revised proposal sent to the Secretary for initial comment May 23, 2013. Secretary attended June 19, 2013 Board Meeting. Public Notice for initial comments posted July 11, 2013. Proposed regulations to be reviewed by Board Committees and the Sterile Compounding Subcommittee to be approved by the full Board at the November 20, 2013 Board Meeting. The Board approved designating the Sterile Compounding Subcommittee to represent the Board in reviewing drafts. Members of the Sterile Compounding Subcommittee are also members of other Board committees and may poll their committees if necessary. The final proposal will be approved by the full Board. **Board approval requested for responses to comments received: The Board approved the following responses:** **1) Draft Board Response to KP and MSHP** **Kaiser Permanente_Sterile Compounding Comments_7.25.13** **Sterile Compounding_Statue Questions 2013 MSHP Response Final** Dear Dr. Hurley, Dr. Swarthout, and Dr. Saha: Thank you for providing comments in reference to the HB 986 State Board of Pharmacy – Sterile Compounding – Permits, Chapter 397, 2013, (HB986), prior to the promulgation of the regulations. The	**10.34.03** – Inpatient Institutional Pharmacies. No action taken. **10.34.19** Sterile Pharmaceutical Compounding. Motion by D. Jones to have Sterile Compounding Subcommittee represent the Board in reviewing drafts of proposed sterile compounding regulations. Motion was seconded by M. Souranis. 1. Motion by M. Gavgani to approve draft Board response to Kaiser Permanente and the Maryland Society of Health System Pharmacists, as stated in these minutes. Motion was seconded by D. Jones.	Motion was approved. Motion was approved.

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		Board's solicitation for comment included a series of questions for stakeholders to consider. Those questions are set forth below with a summary of comments received from both Kaiser Permanente and the Maryland Society of Health System Pharmacists followed by the Board's response. **1. What special requirements for sterile compounding should the Board consider?** It was suggested that the Board consider the following special requirements for sterile compounding: **a. Federal legislative impact.** It was noted that there are inconsistencies between the proposed federal legislation and HB 986. The proposed federal legislation does not allow a compounding manufacturer to register as a pharmacy in any state so that there is a clear distinction between federal and state oversight. This is problematic for those entities that perform sterile compounding and also manufacture sterile drug products. The Board is following the federal legislation and understands that revisions may need to be made to the new Subtitle 4A. Sterile Compounding Permits, in the future. **b. Transfer of products within health systems.** It was suggested that the Board consider in the proposed regulations the transfer of patient specific compounded medications within a hospital's pharmacies or a health system's pharmacies. Please be advised that these types of transfers may be considered "intracompany" and would not be subject to HB 986. **c. Transfer between health systems.**		

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		It was also suggested that the Board consider allowing the transfer of sterile compounds between hospitals or health systems to occur when needed urgently for patient care. The Board is taking into consideration, and HB 986 accommodates, drug shortages. Transfers between health systems are not "intracompany" and would be subject to HB 986. **2. What are such exigent circumstances that might necessitate a waiver?** It was suggested that the Board consider the following categories of exigent circumstances that may necessitate a waiver: **a. Drug Shortages.** HB 986 was crafted to address drug shortages and a mechanism for the provision of compounded medications and sterile drug products to Maryland citizens when there is a true drug shortage. **b. Emergent In-Office Use.** It was pointed out that the ability to obtain non-patient specific sterile compounds for emergent in-office use is critical for the immediate treatment of urgent conditions that require timely administration of medications to prevent negative health care outcomes. It was recommended that the definition of "emergent" include any diagnosis where treatment with a sterile compounded medication within 72 business hours is clinically necessary to prevent adverse health outcomes. The Board notes that within a 72 hour window a patient specific prescription could be made available to obtain the medications needed and would not be an emergent reason for a waiver. In addition, compounding under urgent conditions becomes a patient safety risk.		

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		Additionally, the Board will place in the proposed regulations a provision that does not allow a waiver based on criteria based on financial or business concerns. The Board believes this supports the intent of the legislation that allows a waiver for which there is a clinical need and there are emergent circumstances that, as determined by the Board, otherwise prevent health care providers from obtaining, in the size and strength needed, the specified sterile compounded preparations or sterile drug products for which there is a clinical need. **c. Non-Compounding Manufacturers** It was suggested that entities that could not obtain an FDA permit be automatically waived from the requirements of a wholesale distributor permit. Additionally, it was noted that federal legislation is pending that precludes an entity that is licensed as a pharmacy from receiving a compounding manufacturer permit from the FDA in order to differentiate between federal and state oversight. Those entities that have dual business purposes, patient specific and sterile drug products would not be able to register with the FDA and would not be eligible to ship non-patient specific sterile drug products into MD without a waiver. The Board notes that this is the intent of HB 986 – to provide a mechanism to provide a waiver for those entities that do not qualify for a sterile compounding permit or are not able to obtain an FDA permit and to know exactly which entities are dispensing or distributing sterile drug products to Maryland citizens. A suggestion for dual business entities that perform patient specific compounding and compound sterile drug products would be for those entities to establish separate entities for each purpose.		

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		d. USP 797 low risk compounding It was suggested that hospitals and health systems that only prepare low risk compounds, as defined in USP <797>, be eligible for a sterile compounding permit waiver. The waiver is not intended for pharmacies that are compounding as defined in USP <797>. Pharmacies performing compounding under USP <797> are required to obtain the Sterile Compounding Permit. **3. What are examples of specific sterile products and clinical situations that might meet criteria for such a waiver?** Several comments were received which listed specific sterile products and clinical situations that might meet the criteria for a waiver. HB 986 is very specific when a waiver may be issued. HB 986 sets forth that the Board may issue a waiver of the Maryland requirements for FDA manufacturers to a person that prepares and distributes sterile drug products into, out of, or within the State only for a specified sterile drug product where exigent circumstances exist. The criteria for exigent circumstances may include that the specified sterile drug product is listed on the current drug shortages index by the U.S. Food and Drug Administration or the specified drug product is only prepared and distributed by the person applying for the waiver. Additionally, the absence of the specified sterile drug product would result in a patient care or a patient safety risk may be considered. Clinical need will be determined by the Board with input from health care providers in the State such as the Maryland Hospital Association; the Maryland Society of Health-Systems Pharmacists; the Maryland State Medical Society; and other relevant professionals as determined by the Board. The criteria may not be based on financial or business concerns; **4. What process can the Board use to keep a current list of**		

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		products for which there is a need for a waiver? It was suggested that the Board form an expert taskforce with representation from different areas of pharmacy to review, approve, and oversee the list of products for which there is a need for a waiver with final approval of the list by the Board. The Board plans to use the FDA Drug Shortage List when considering granting a waiver. **5. In addition to provision of reports of inspections, a statement of compliance with USP 797, and review and report of any adverse regulatory action, what else should be required of people or facilities producing and distributing "waived" sterile products?** No additional requirements were suggested in the comments received. **6. How can the Board know when the need for a "waived" sterile product no longer exists?** It was suggested that the expert taskforce suggested above would be responsible for reviewing the list of "waiver" sterile products and make recommendation to the Board regarding when the need for a product wavier no longer exists. The Board plans to use the FDA Drug Shortage List when considering the need to continue a waiver. **7. Should there be an emergency waiver process, and if so, when would that be needed and how might that work?**		

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		There was a suggestion that an emergency waiver process be available for short notice drug shortages caused by urgent recalls or other emergent situations, including natural disasters. It was also suggested that facilities be allowed to compound to meet urgent needs while their waiver application is pending. HB 986 establishes a process to allow for waivers for exigent circumstances. For situations that require immediate action, specifically during natural disasters or federal or State emergencies, the Secretary may override HB 986 and allow for the necessary compounding to meet the health needs of Marylanders. **8. Additional comments.** It was suggested that formal training be conducted for Board of Pharmacy inspectors concerning USP <797>. Please know that the Board's inspectors have received extensive training in USP <797> as COMAR 10.34.19 Sterile Pharmaceutical Compounding has been effective since 2009 incorporating all the revisions to USP <797>. The Board inspects all pharmacies annually and has been thoroughly inspecting compounding pharmacies for compliance with USP <797> since 2009. It was suggested that annual inspections of pharmacies, and annual inspections of those pharmacies that hold sterile compounding permits, occur at the same time. The Board is conscious of preserving resources and will make every effort to inspect pharmacies, regardless of permit status, only once a year, unless otherwise warranted. It was also suggested that decentralized pharmacies within a hospital system have clear direction regarding sterile compounding. All pharmacies that obtain a sterile compounding permit will be subject to the same laws and regulations.		

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		Thank you again for your thorough consideration of the solicitation for comment posted on the Department of Health and Mental Hygiene's website. Drafts of the regulations will be released informally this fall. Please also monitor the Maryland Register for the initial publication of the proposed revisions to COMAR 10.34.19 Sterile Pharmaceutical Compounding. http://www.dsd.state.md.us/MDRegister/mdregister.aspx A 30 day comment period will follow. Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794. **2) Draft Board Response to Md Society of Eye Surgeons** **July 25 comp pharmacy response-MD Soc Eye Phy and Surgeons** **Md Society of Eye Physicians Surgeons 072913** Dear Dr. Morgan: Thank you for providing comments in reference to the HB 986 State Board of Pharmacy – Sterile Compounding – Permits, Chapter 397, 2013, (HB986), prior to the promulgation of the regulations. The Maryland Society of Eye Physicians and Surgeons urged the Board to include office use exemptions for compounded biologics and other FDA marketed drugs to ensure that ophthalmologists have access to them for their patients to receive critical, sight-saving treatment. Please be advised that the law in Maryland is clear. Health Occupations Article, 12-101, Annotated Code of Maryland. HB 986 has not changed this definition. "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:	2. Motion by M. Gavgani to approve the draft Board response to the Maryland Society of Eye Physicians, as stated in these minutes. Motion was seconded by H. Finke.	Motion was approved.

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		(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or (ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device. "Compounding" includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns. Compounded medications obtained for office use that are commercially available may be purchased from an FDA manufacturer. For those compounded medications that are not commercially available, and there is an emergent need as determined by the Board using the criteria in HB 986, there will be a waiver available. The waiver is intended for entities that are licensed as wholesale distributors and where there is no FDA permit available. Thank you again for your thorough consideration of the solicitation for comment posted on the Department of Health and Mental Hygiene's website. Drafts of the proposed regulations will be released informally this fall. Please also monitor the Maryland Register for the initial publication of the proposed revisions to COMAR 10.34.19 Sterile Pharmaceutical Compounding. http://www.dsd.state.md.us/MDRegister/mdregister.aspx A 30 day comment period will follow. **3) Draft Board Response to Pet Owners** **Schultheiss - Vet 072413** Thank you for providing comments in reference to the HB 986 State Board of Pharmacy – Sterile Compounding – Permits, Chapter 397, 2013, (HB986), prior to the promulgation of the regulations.	3. Motion by J. Smith to approve draft Board response to pet owners as stated in these minutes. Motion was seconded by	Motion was approved.

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		HB 986 applies to sterile compounding only. Many compounded pet medications are not sterile under USP <797> and HB 986 does not apply to those compounds. The purpose of HB 986 and the pending regulations is to ensure the quality and safety of the drugs that pets receive. Until the new sterile compounding laws become effective (both State and federal), veterinarians may continue to compound and dispense sterile products in accordance with applicable standards of practice. Veterinarians may compound a limited quantity of a particular medication in anticipation of immediate future need as based on previously documented prescriptions filled for that medication. Veterinarians who wish to engage in sterile compounding after the implementation of the new Maryland law must obtain an additional permit from the Board of Pharmacy and comply with certain minimum standards. Veterinarians who compound non-sterile products do not require an additional permit from the Board. If using a pharmacy, a pharmacy would have the ability to compound in anticipation of receipt of a patient specific prescription. Any compounded prescription that is dispensed must be pursuant to a patient specific prescription. See COMAR 10.34.19.08. This regulation may provide a solution to some veterinarian concerns. The veterinarian should work with the pharmacy to arrange availability in emergency situations. Thank you again for your thorough consideration of the solicitation for comment posted on the Department of Health and Mental Hygiene's website. Drafts of the proposed regulations will be released informally. Please monitor the Maryland Register for the initial publication of the proposed revisions to COMAR 10.34.19 Sterile Pharmaceutical Compounding. http://www.dsd.state.md.us/MDRegister/mdregister.aspx A 30 day	M. Souranis.	

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		comment period will follow. **4) Draft Board Response to St. Agnes** **St. Agnes - Gregory Smith 071513** Dear Mr. Smith: Thank you for providing comments in reference to the HB 986 State Board of Pharmacy – Sterile Compounding – Permits, Chapter 397, 2013, (HB986), prior to the promulgation of the regulations. Below are responses to your questions: **Does this pertain to compounding for own use?** HB 986 pertains to compounding pursuant to a patient specific prescription and also to the preparation of sterile drug products which are prepared using aseptic techniques and are not required to be prepared in response to a patient specific prescription. **Do hospitals need to get the additional permit?** All pharmacies licensed in Maryland will be required to obtain a sterile compounding permit if they are performing sterile compounding. **Is there a difference between anticipatory compounding and patient specific?** Yes. Please see COMAR 10.34.19.08 which pertains to "batch preparation" or anticipatory compounding. Patient specific prescriptions are the basis for "batch preparations." **.08 Batch Preparation.** A. A pharmacist may prepare batched sterile preparations for future use in limited quantities	4. Motion by D. Jones to approve draft Board response to Gregory Smith of St. Agnes Hospital, as stated in these minutes. Motion was seconded by M. Gavgani.	Motion was approved.

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		supported by prior valid prescriptions or physician orders before receiving a valid written prescription or medication order. B. Batch preparation of specific compounded sterile preparations is acceptable if the: (1) Pharmacist can document a history of valid prescriptions or physician orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship; and (2) Pharmacy maintains the prescription on file for such preparations dispensed. **Will there be different standards based on whether the compound is low risk, medium risk, or high risk?** No. **Shipping concerns due to environment (temperature) and security.** Please see COMAR 10.34.25 Delivery of Prescriptions, which applies to shipping of all prescription medications by a Maryland pharmacy. Thank you again for your thorough consideration of the solicitation for comment posted on the Department of Health and Mental Hygiene's website. Drafts of the proposed regulations will be released informally. Please monitor the Maryland Register for the initial publication of the proposed revisions to COMAR 10.34.19 Sterile Pharmaceutical Compounding. http://www.dsd.state.md.us/MDRegister/mdregister.aspx A 30 day comment period will follow.		

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		5) Draft Board Response to Veterinarians **Vet Center - Dr. Cox 071713** **Jeffers, VMD - Vet 072613** **Burke-Schwarz - Vet 072213** **Soverns - Vet 072413** **Townsend - Vet 072213** **Rubenstein - Vet 072213** **Rubenstein II - Vet 072313** Thank you for providing comments in reference to the HB 986 State Board of Pharmacy – Sterile Compounding – Permits, Chapter 397, 2013, (HB986), prior to the promulgation of the regulations. Until the new sterile compounding laws become effective (both State and federal), veterinarians may continue to compound and dispense sterile products in accordance with applicable standards of practice to their patients only. Keep in mind that HB 986 applies to sterile compounding only. Veterinarians may compound a limited quantity of a particular medication in anticipation of immediate future need as based on previously documented prescriptions filled for that medication. Veterinarians who wish to engage in sterile compounding after the implementation of the new Maryland law must obtain an additional permit from the Board of Pharmacy and comply with certain minimum standards. Veterinarians who compound non-sterile products do not require an additional permit from the Board. If using a pharmacy, a pharmacy would have the ability to compound in anticipation of receipt of a patient specific prescription. Any compounded prescription that is dispensed must be	5. Motion by J. Smith to approve draft Board response to veterinarians, as stated in these minutes. Motion was seconded by M. Souranis.	Motion was approved.

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		pursuant to a patient specific prescription. See COMAR 10.34.19.08. This regulation may provide a solution to some veterinarian concerns. The veterinarian should work with the pharmacy to arrange availability in emergency situations. Thank you again for your thorough consideration of the solicitation for comment posted on the Department of Health and Mental Hygiene's website. Drafts of the proposed regulations will be released informally. Please monitor the Maryland Register for the initial publication of the proposed revisions to COMAR 10.34.19 Sterile Pharmaceutical Compounding. http://www.dsd.state.md.us/MDRegister/mdregister.aspx A 30 day comment period will follow. **10.34.22 – Licensing of Wholesale Prescription Drug or Device Distributors** Submitted July 23, 2013 to DHMH for sign-off and publication. Further revisions discussed at August Practice Committee. **Board approval requested for:** **Wholesale Distributor regs - 10.34.22 and 10.34.37 092013 Bd Mtg** The Board approved the proposal for submission into the regulatory process for publication in the Maryland Register. **10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities** Effective September 16, 2013. **10.34.32 Pharmacist Administration of Vaccinations** **Board approval requested for the proposal:**	Motion by M. Souranis to approve the proposal for submission into the regulatory process for publication in the Maryland Register of Wholesale Distributor Regulations 10.34.22 and 10.34.37. Motion was seconded by H. Finke.	

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		Proposed COMAR 10.34.32 - for Sept 20 Bd Mtg The Board approved the proposal with a revisions to Regulation .08 Fees, for submission into the regulatory process as an **Emergency Proposal** for publication in the Maryland Register. **10.34.33 Prescription Drug Repository Program** Proposal to be revised pursuant to federal regulations. **Federal Register** / Vol. 77, No. 246 / Friday, December 21, 2012 / Proposed Rules. Linda Bethman briefly explained that the Federal proposed regulations included provisions for mail back envelopes and one way bins for disposal. The one way bins would be sent to a reverse distributor for disposal. She asked the Board if they would like to include in COMAR 10.34.33 the higher federal standards for disposal of CDS for all prescription medications disposed of in Md. The regulations would increase in size and scope substantially. The Board referred this issue to the Practice Committee. **10.13.01 Dispensing of Prescription Drugs by a Licensee** TBD **LEGISLATION:** 1) Consumer Board Members – Proposal submitted July 19, 2013.	Motion by S. Roy to approve revision to Regulation .08 "Fees"of **10.34.32 "Pharmacist Administration of Vaccinations" for** submission into the regulatory process as an Emergency Proposal for publication in the Maryland Register. Motion was seconded by Z. St. Cyr, II. **10.34.33 Prescription Drug Repository Program -R**eferred to the Practice Committee. 1. Consumer Board Members – Proposal	Motion was approved.

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		2) Graduate Intern Legislation – Discussion of when the intern permit would begin. Other states laws: **PharmacyInternComparison - State Laws** Discussion ensued regarding when a pharmacy student would be eligible for the new internship category. It was suggested that the internship category begin the first year of pharmacy school, for four years only, with direct supervision. It was mentioned that the supervising pharmacist would be responsible for the students. There was also a suggestion that a student exemption, verified very year, would simplify the process. There were concerns expressed that 1st year pharmacy students would not be qualified to do the same pharmacy tasks as pharmacy students with more experience. The Board referred this issue to the Practice Committee. 3) 10 mile radius legislation hold for future discussion 4) Mandatory CE course regarding recognizing and reporting child abuse. The Board recommended asking if pharmacy could be waived. It would be better to educate licensees with Newsletter Articles to	submitted July 19, 2013. No action needed 2. Graduate Intern Legislation – Referred to the Practice Committee. 3. 10 Mile Radius legislation – Held for future discussion. No action taken. 4. Mandatory CE course	

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		increase awareness of the issue. Commissioner Gavgani indicated that no CE's on this topic exist with the approved organizations. Would definitely want wholesale distributors exempt since they do not distribute to patients or consumers. **REPORTS:** **Board approval requested for:** **The Maryland Board of Pharmacy Report to the Senate EHE and House HGO Committees on the Implementation of Nonstatutory Recommendations contained in the October 2011 Sunset Evaluation Report.** The Board referred this issue to the Practice Committee and then to the Executive Committee for final approval. May occur through email. **MEETINGS:** 1) Prescription Drug Repository Program – September 5, 2013 – discussion of potential Maryland regulations after the Federal regulations are final. 2) Delores Kelly is holding a meeting in Annapolis on October 8,	regarding recognizing and reporting child abuse. The Board recommended asking if pharmacy could be waived. It would be better to educate licensees with Newsletter Articles to increase awareness of the issue. Motion by M. Souranis to refer to the Practice Committee the Board's Report to the Senate EHE and House HGO Committees on the Implementation of Nonstatutory Recommendations contained in the October 2011 Sunset Evaluation Report. Final review to be by the Executive Committee. Motion was seconded by Z. St. Cyr.	Motion was approved.

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III. Committee Reports **A. Practice Committee**	H. Finke, Chair	2013 at 11:00 am regarding possible legislation to allow patients to be discharge from hospitals with filled prescriptions. . David Jones, Sajal Roy, Harry Finke, and Mike Souranis expressed an interest in attending this meeting. Anna Jeffers will forward Senator Kelley's initial letter to them. Commissioner Rochester recognized that there are serious transition issues when patients leave the hospital. 4) NABP – Item Development Workshop – March 20/21st 2014 **Inquiries:** **1.** Soumi Saha, KP **Kaiser Permanente_Return to Stock to Automated Medication Systems_Supplemental Comments_7.19.13** **DRAFT Bd Response-KP-Return to stock to AMS** **The Board approved the following response:** Thank you for contacting the Maryland Board of Pharmacy concerning clarification around what is required under COMAR 10.34.28.08(C) which states "*Unused medications dispensed from a centralized automated medication system stocked with bulk medications may not be returned to the system*." Specifically, Kaiser Permanente has requested clarification around what is meant by "dispensed" and how it pertains to centralized automated medication systems in light of technological advances. As technology advances, the Board recognizes that it may need to revisit COMAR 10.34.28 Automated Medication Systems, to ensure that the chapter is consistent with upgrades in technology. A consideration of revisions to COMAR 10.34.28 will be forthcoming.	1. Motion by Practice Committee to approve draft Board response to Soumi Saha of Kaiser Permanente as stated in these minutes. Motion was seconded by M. Souranis.	Motion was approved.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		2. Stephanie Dress, RN **10.34.35.03 - nurses as designees in oncology clinics** **10.34.35.01 - .10 060412** **DRAFT Bd Response-Nurses as designees in oncology clinics** **The Board approved the following response:** Thank you for contacting the Maryland Board of Pharmacy concerning whether under COMAR 10.34.35.03 Infusion Pharmacy Services in an Alternate Site Care Environment, a nurse may be a designee of a pharmacist to mix chemotherapy and premeds (i.e. benadryl, dexamethasone, etc) at an alternate site such as an outpatient oncology clinic. COMAR 10.34.35 regulates the practice of pharmacists when performing infusion pharmacy services for patients in an alternate site care environment. The infusion pharmacy services referenced in this chapter would be performed in a pharmacy. Any designee would be a registered pharmacy technician, a pharmacy student under an experiential learning program of a school of pharmacy, or a pharmacist working in a pharmacy under the direct supervision of a pharmacist while obtaining the requisite hours for licensure. Pharmacists do not supervise nurses or designate pharmacy activities to nurses. If a nurse is mixing chemotherapy and premeds in an outpatient oncology clinic it would probably be under the supervision of a physician and COMAR 10.34.35 would not apply. Please contact Dr. Koya at the Maryland Board of Physicians regarding your question. yemisi.koya@maryland.gov For your information, HB 986 State Board of Pharmacy – Sterile Compounding – Permit, passed in the 2013 Legislation Session. Although effective July 1, 2013 it will not be fully implemented	2. Motion by Practice Committee to approve the draft Board response to Stephanie Dress as stated in these minutes. Motion was seconded by M. Souranis.	Motion was approved.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		until April 1, 2014. Under HB 986, any setting in which sterile compounding is performed will be required to obtain a sterile compounding permit from the Board of Pharmacy. More information on the application procedure will be forthcoming on the Board of Pharmacy website in the next few months. **3. Information Only – Under current Maryland Law Pharmacies, whether repositories or not, may not receive outdated physician samples.**	3. No action needed, FYI only.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
B. Licensing Committee	L. Bradley-Baker, Chair,	**1. Review of Pharmacy Applications:** • A. **Linden Care Inc**. - Requesting extension of time to obtain a MD pharmacy permit. Licensing Committee recommendation is to deny request and to inform Linden that they cannot be licensed without meeting all requirements and cannot operate in MD under old permit. **2. New Business:** • A. **Woodland Hills Pharmacy** - Would like refund of $700 application fee as they downloaded application off of Board of Pharmacy website that did not state that they needed a MD licensed pharmacist on staff, nor did the application state that the application fee was nonrefundable. Licensing Committee recommendation is to deny request as it is an administrative fee. • **B. CE Monitor Program -** Would like to adopt the CME Monitor Program for Pharmacist and Technicians and remove the CE requirement sheet from all applications. Will add information to renewal application and a field in the database.	1 A. Motion by Licensing Committee to deny request of Linden Care, Inc. an to inform Linden that they cannot be licensed without meeting all requirements and cannot operate under old permit. Motion was seconded by M. Gavgani. 2. A. Motion by Licensing Committee to deny the request for refund of application fee by Woodland Hills Pharmacy as it is an administrative fee. Motion was seconded by M. Gavgani. 2. B. Motion by Licensing Committee to adopt the CME Monitor Program for Pharmacist and Technicians and to remove the CE requirement sheet from all applications. Licensing Committee will add information to renewal application and place a field in the database. Motion was seconded by D. Jones.	Motion was approved. \ Motion was approved. Motion was approved.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		• **C. Graduate Intern Bill** - Discussion of Bill regarding foreign grads and pharmacy graduates. Licensing Committee recommendation is to eliminate pharmacy technician student exemption status and create pharmacy intern registration: Allow all pharmacy school students (U.S. and foreign)to apply for four year registrations expiring 12/31 with a fee of $45.	2. C. Graduate Intern Bill was discussed above in Section II. F. Legislation and Regulations.	
C. Public Relations Committee	L. Bradley-Baker, Chair	Public Relations Committee Update: • Public Outreach Events: 1. The Board is proud to be a Silver Sponsor of the Maryland Pharmacists Association MTM (Medication Therapy Management) Summit which will be held on September 28 & 29, 2013 at Montgomery Park. 2. The Board's annual CE Breakfast to be held October 6, 2013 is already completely booked and the Board has a waiting list for this event which has been moved from The Radission at Cross Keys to the BWI Hyatt. The Board will be placing this program discussing Maryland's Prescription Drug Monitoring Program on the Board's website. It will not be available for CE credit but will be available for information purposes. 3. Peggy Funk, Acting Executive Director of the Maryland Pharmacists Association (MPhA) has offered the Board space in its quarterly journal as well as its monthly electronic newsletter and its weekly Monday electronic e-mails for the Board to enhance the Board's communication to pharmacists. After discussion it was decided to speak with Maryland Pharmacy Coalition to extend opportunity to all Pharmacy Association to participate as (MPhA) has offered.		

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D. Disciplinary	M. Gavgani, Chair	Disciplinary Committee Update – No update this month.		
E. Emergency Preparedness Task Force	L. Bradley-Baker, Acting Chair	Emergency Preparedness Task Force Update : The EPTF will participate in a statewide drill , under Maryland's Department of Health and Mental Hygiene to be held September 24 - 26, 2013. The Task Force members will be responsible for quality assurance of product to be shipped to a point of distribution site. And to recruit pharmacists and pharmacy technicians to assist in the quality control of this drill.		
IV. Other Business & FYI	L. Israbian-Jamgochian, President	President L. Israbian-Jamgochain extended an invitation to the public to ask questions and there was a brief discussion concerning graduate interns and new regulations on vaccinations.		
V. Adjournment	L. Israbian-Jamgochian, President	The Public Meeting was adjourned at 12:10 P.M. At 1:11 P.M. L. Israbian-Jamgochian convened a Closed Public Session to conduct a medical review of technician applications. C. The Closed Public Session was adjourned at 1:20 P.M. Immediately thereafter, H. Finke convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.	Motion by M. Souranis to adjourn the Public Board meeting pursuant to State Government Article 10-508)a)(13) and (7) for the purpose of engaging in medical review committee review deliberation regarding confidential matters in applications Meeting. The motion was seconded by Z. St. Cyr.	Motion was approved.